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ATTORNEYS AT LAW

Docket No.: 242579US0CONT

COMMISSIONER FOR PATENTS
ALEXANDRIA, VIRGINIA 22313

RE: Application Serial No.: 10/687,709
Applicants: Shigeru KAWAHARA, et al.
Filing Date: October 20, 2003
For: PROCESS FOR PRODUCING N-FORMYLAMINO ACID AND USE THEREOF
Attention: Applications Division

SIR:

Attached hereto for filing are the following papers:

Form PCT/IB/338

English Translation of International Preliminary Examination Report

Our check in the amount of **$0.00** is attached covering any required fees. In the event any variance exists between the amount enclosed and the Patent Office charges for filing the above-noted documents, including any fees required under 37 C.F.R 1.136 for any necessary Extension of Time to make the filing of the attached documents timely, please charge or credit the difference to our Deposit Account No. 15-0030. Further, if these papers are not considered timely filed, then a petition is hereby made under 37 C.F.R. 1.136 for the necessary extension of time. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

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PATENT COOPERATION TREATY

PCT

NOTIFICATION OF TRANSMITTAL OF COPIES OF TRANSLATION OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 72.2)

From the INTERNATIONAL BUREAU

To:

ISHIDA, Yasumasa
A. Kato & Associates
Bohsei Bldg., 7th Floor, 20-12,
Shin-Yokohama 3-chome, Kohoku-ku
Yokohama-shi, Kanagawa 222-0033
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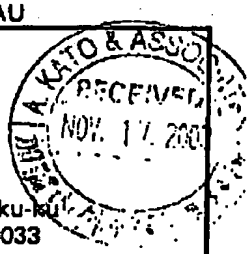

Date of mailing (day/month/year) 04 November 2003 (04.11.03)	
Applicant's or agent's file reference P2697PCT-AJ	IMPORTANT NOTIFICATION
International application No. PCT/JP02/03754	International filing date (day/month/year) 16 April 2002 (16.04.02)
Applicant AJINOMOTO CO., INC. et al	

1. Transmittal of the translation to the applicant.

The International Bureau transmits herewith a copy of the English translation made by the International Bureau of the international preliminary examination report established by the International Preliminary Examining Authority.

2. Transmittal of the copy of the translation to the elected Offices.

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following elected Offices requiring such translation:

EP,CA,CN,KP,RO,US

The following elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

AP,EA,AE,AG,AL,AM,AT,AU,AZ,BA,BB,BG,BR,BY,BZ,CH,CO,CR,CU,CZ,DE,DK,DM,DZ,EC,EE,ES, FI,GB,GD,GE,GH,GM,HR,HU,ID,IL,IN,IS,JP,KE,KG,KR,KZ,LC,LK,LR,LS,LT,LU,LV,MA,MD,MG, MK,MN,MW,MX,MZ,NO,NZ,OM,PH,PL,PT,RU,SD,SE,SG,SI,SK,SL,TJ,TM,TN,TR,TT,TZ,UA,UG,UZ, VN,YU,ZA,ZM,ZW,OA

3. Reminder regarding translation into (one of) the official language(s) of the elected Office(s).

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report.

It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland
Facsimile No. (41-22) 338.70.10

Authorized officer

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Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P2697PCT-AJ	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/JP02/03754	International filing date (*day/month/year*) 16 April 2002 (16.04.02)	Priority date (*day/month/year*) 20 April 2001 (20.04.01)
International Patent Classification (IPC) or national classification and IPC C07C 231/02, 231/08, 233/47, C07K 1/06, 1/30, 5/075, C12P 21/02		
Applicant AJINOMOTO CO., INC.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 8 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☒ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
22 October 2002 (22.10.02)	25 April 2003 (25.04.2003)
Name and mailing address of the IPEA/JP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/JP02/03754

I. Basis of the report

1. With regard to the elements of the international application:*

☒ the international application as originally filed

☐ the description:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the claims:

pages _____, as originally filed
pages _____, as amended (together with any statement under Article 19
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the drawings:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the sequence listing part of the description:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____
☐ the claims, Nos. _____
☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/JP02/03754

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

☐ restricted the claims.

☒ paid additional fees.

☐ paid additional fees under protest.

☐ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

☐ complied with.

☒ not complied with for the following reasons:

See supplemental sheet

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

☒ all parts.

☐ the parts relating to claims Nos. _____ .

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: IV. 3.

The special technical feature shared by Claims 1-3, 5, 7, 9, 14 and 15, and by Claims 10, 12 and 13 in as much as they refer to Claims 5, 7 and 9 (inventions of group A), is a "process wherein an amino acid or salt thereof is reacted with formamide and/or methyl formate to produce an N-formylamino acid or a salt thereof".

The special technical feature shared by Claims 4, 6 and 8, and by Claims 10, 12 and 13 in as much as they refer to Claims 4, 6 and 8 (inventions of group B), is a "process wherein N-formyl-L-aspartic acid or a salt thereof is subjected to an enzyme catalysed condensation reaction with L and/or DL-phenylalanine methyl ester or a salt thereof, to produce N-formyl-α-L-aspartyl-L-phenylalanine methyl ester or an adduct thereof with L and/or DL-phenylalanine methyl ester".

The special technical feature shared by Claim 11, and by Claim 13 in as much as it refers to Claim 11 (inventions of group C), is a "process whereby a phenylalanine methyl ester adduct of N-formyl-α-L-aspartyl-L-phenylalanine methyl ester is converted to N-formyl-α-L-aspartyl-L-phenylalanine methyl ester".

The inventions of group A, in part, and the inventions of group B both relate to "N-formyl-L-aspartic acid or a salt thereof"; however, this is clearly not a special technical feature.

Similarly the inventions in groups B and C both relate to "N-formyl-α-L-aspartyl-L-phenylalanine methyl ester", but this is also clearly not a special technical feature.

The inventions in groups A and C do not share a common feature.

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: IV. 3.

The inventions in groups A-C thus do not share a special technical feature, and these three groups of inventions are not so linked as to form a single general inventive concept.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/JP 02/03754

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	3-5, 7-9, 12	YES
	Claims	1,2,6,10,11,13-15	NO
Inventive step (IS)	Claims		YES
	Claims	1-15	NO
Industrial applicability (IA)	Claims	1-15	YES
	Claims		NO

2. Citations and explanations

Document 1: US, 4801742, A (W. R. Grace & Co., Conn), 31 January 1989

Document 2: WO, 98/16546, A (Holland Sweetener Company V.O.F), 23 April 1998

Document 3: JP, 2000-78997, A (Dainichiseika Color & Chemical Mfg. Co., Ltd.), 21 March 2000

(Documents 1-3 are cited in the international search report.)

Document 1 discloses a process wherein the salt of an amino acid such as aspartic acid is reacted with methyl formate to obtain an N-formylamino acid (see claims and examples), and mentions that the salt of an amino acid such as aspartic acid can be prepared by bringing the amino acid into contact with a base (see column 3, lines 3-21). Therefore, Claims 1, 2, 14 and 15 are not novel and do not involve an inventive step.

Document 2 discloses as prior art a process wherein N-formyl-L-aspartic acid and L-phenylalanine methyl ester undergo enzyme-catalysed condensation, and the resulting phenylalanine methyl ester adduct of N-formyl-α-L-aspartyl-L-phenylalanine methyl ester is floated in water

and the pH of the water corrected to 1.6 in order to obtain N-formyl-α-L-aspartyl-L-phenylalanine methyl ester (see page 2, lines 3-12). Therefore, Claims 11 and 13 are not novel and do not involve an inventive step.

A person skilled in the art could easily use N-formylaspartic acid obtained by the process disclosed in Document 1 as the starting material for said process disclosed in Document 2; therefore Claim 3 does not involve an inventive step.

Document 2 discloses a process for synthesizing N-formyl-α-L-aspartyl-L-phenylalanine methyl ester by enzyme catalysed condensation of N-formyl-L-aspartic acid and L-phenylalanine methyl ester wherein an organic phase comprising a solvent non-miscible with water, such as tributylphosphoric acid, is fed to the aqueous solution phase, so that as the condensation reaction proceeds in the aqueous phase the N-formyl-α-L-aspartyl-L-phenyl-alanine methyl ester migrates into the organic phase (see claims, and especially Claim 3). Therefore, Claims 6 and 10 are not novel and do not involve an inventive step.

A person skilled in the art could easily use N-formylaspartic acid obtained by the process disclosed in Document 1 as the starting material for said process disclosed in Document 2; therefore Claim 7 does not involve an inventive step.

A person skilled in the art could easily conceive of combining the aforementioned two processes disclosed in Document 2; therefore, Claim 12 does not involve an inventive step.

Document 3 discloses a process for synthesizing a peptide by reacting an N-substituted aspartic acid

derivative with a lower alkyl ester of phenylalanine in the presence of a protease, wherein the aqueous solution is used as a paste in which the concentration of the N-substituted aspartic acid derivative is a concentration upwards of its solubility in water (see the claims). A person skilled in the art could easily set a suitable specific concentration for the N-substituted aspartic acid derivative. Therefore Claims 4 and 10 do not involve an inventive step.

A person skilled in the art could easily use N-formylaspartic acid obtained by the process disclosed in Document 1 as the starting material for the process disclosed in Document 3; therefore Claim 5 does not involve an inventive step.

A person skilled in the art could also further conceive of combining the two processes disclosed in Document 2 and the process disclosed in Document 3. Therefore, Claims 8, 9, 12 and 13 do not involve an inventive step.